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Interventions for improving health literacy in migrants (Protocol)

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[Intervention Protocol]

Interventions for improving health literacy in migrants

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

- To assess the effectiveness of interventions for improving health literacy in migrants.
- To assess whether female or male migrants may respond differently to the identified interventions.

Such interventions must address health literacy either as a comprehensive construct or at least one of its four health information processing steps (access, understand, appraise, apply). However, we do not aim to equate general health literacy interventions that include a range of activities targeted to all of the four health information processing steps with interventions that aim to improve only one step (e.g. understand). We aim instead to create a comprehensive picture of the effect of health literacy interventions by applying the integrated model as an umbrella framework for a deductive analysis of the four steps of health information processing.

We will not restrict this review to specific settings or diseases because we aim to provide an overview of all available interventions for improving health literacy addressing migrant populations.

Extending this review with a qualitative evidence synthesis

The author team of this effectiveness review will conduct a qualitative evidence synthesis (QES) in parallel: *Gender differences in health literacy of migrants: a synthesis of qualitative evidence* (Aldin 2019). Since we expect that relatively few studies will explicitly aim to explore if female and male migrants respond differently to a selected health literacy intervention, or even contain data on female and male migrants that can be extracted separately, the QES will supplement the effectiveness review in terms of gender-specific aspects that can affect the health information processing steps. Additionally, it will attempt to identify factors associated with gender and migration that may play a role in the design, delivery and effectiveness of health literacy interventions for female and male migrants,

as it may be able to identify other relevant determinants that cannot be explored by quantitative methods. The QES will be linked to the effectiveness review by using the conceptual framework of health literacy developed by Sørensen 2012. The synthesised evidence from the effectiveness review and the linked QES will ultimately validate the applicability of the integrated model by Sørensen 2012 in interventions for improving health literacy in migrants. On the basis of the joint results, we will develop a logic model that includes the identified factors that must to be taken into account in the development and delivery of health literacy interventions for female and male migrants. The author teams will continuously exchange on methodological issues and support each other within the review process.

BACKGROUND

International migration is a complex phenomenon of increasing importance in an era of rising globalisation. More than ever before, international migration touches all countries and affects all areas of daily living (IOM 2018). The growing presence of migrants, and refugees in particular, can have a complex impact on health care systems of respective host countries that face tremendous pressures of responding fast to new and increasing health care needs (Hunter 2016).

Health literacy has become a key contributor to effective disease management, improved health outcomes and the overall efficiency of health care. Furthermore health literacy is an essential concept with regard to health-related autonomous decisions and behaviour (Woopen 2015). Limitations in health literacy are associated with more frequent hospitalisations and emergency treatments, higher health care expenditures, the reduced use of preventive measures, lower treatment adherence, and an increased risk of morbidity and mortality (Berkman 2011; Eichler 2009; HLS-EU Consortium 2012; Paasche-Orlow 2007; Rasu 2015).

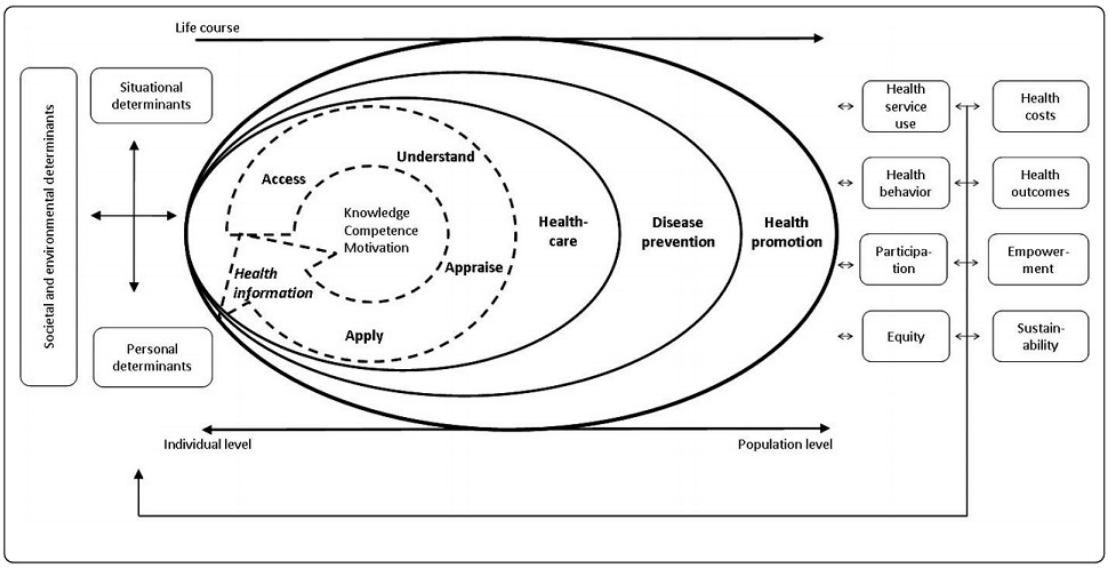
Extensive research exists at the population level among different European countries, suggesting that 47% of the European population have limited or inadequate subjective health literacy (HLS-EU Consortium 2012). Although exact numbers vary across the different countries, all of the results point to a call for action with regard to improving individuals' health literacy (Friis 2016; Pelikan 2013; Schaeffer 2017; van der Heide 2013). Additionally, a recent population study from Germany identified migrants as a high-risk group for limited health literacy, with 71% reporting substantial difficulties in processing health information and translating it into health promoting behaviour (Schaeffer 2017; Quenzel 2016). These results are in line with studies from Australia and the USA that report ethnic minority status as a risk factor for limited health literacy (Adams 2009; Christy 2017; Kutner 2006). Similar critical evidence was found for the health literacy levels of refugees in Sweden (Wångdahl 2014). Thus, improving health literacy, both at the individual and population level, is of crucial importance for a sustainable and equitable promotion of public health.

Description of the condition

Health literacy

The notion of health literacy was initially mentioned in the setting of school-based health education in the 1970s (Simonds 1974). In the medical context, the first definitions referred to health literacy as "the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the healthcare environment" (AMA 1999). This rather passive understanding of the individual acting as a patient - today referred to as functional health literacy - has rapidly expanded to a more complex concept, including individual competencies and resources to take healthy choices and act on health information as an empowered consumer (Nutbeam 2000). To date, a broad variety of definitions and models have evolved around the world (Sørensen 2012). However, until now there is no uniformly applied definition of health literacy. There is little consensus on which combination of individual skills and capabilities constitutes health literacy, or on the areas of life in which these capabilities are applied. Thus, measurements of health literacy are equally diverse, and depend on the underlying definition of health literacy (Altin 2014; Guzys 2015; Haun 2014). Based on a systematic review of existing definitions and conceptual frameworks, Sørensen 2012 developed an integrated model of health literacy by systematically considering individual, social and systemic influencing factors, determinants and domains that can affect individual's health literacy (see Figure 1). Referring to this underlying model, "health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course" (Sørensen 2012). A key component of this definition is the procedural character of health information processing, which is expressed in the following four steps:

Figure 1. Integrated model of health literacy Sørensen 2012



- access;
- understand;
- appraise; and
- apply.

Individual prerequisites such as knowledge, motivation and skills or competencies (e.g. reading and writing abilities) are necessary to pass through the four steps of health information processing. Applying these prerequisites, health literacy requires a person to search for and find relevant health information, to understand it sufficiently, to appraise it in the context of one's own value system, and finally to apply the information, for example, by making healthy choices. Thus, the individual's ability to process health information is closely linked to health-related behaviour (e.g. medication adherence), which can in turn influence health-related outcomes (e.g. progression of disease). However, it is important to note that causes for limited health literacy are not limited exclusively to the individual. Health literacy is determined by individual abilities and resources on the one hand and structural, situational and political conditions on the other hand (Dodson 2015; Parker 2009). For example, a recent migrant might have sufficient health literacy skills to successfully navigate the health care system in the country of origin, but might be challenged by the demands and complexity of the health care system in the host country. Thus, the health literacy environment (e.g. clinicians with intercultural competence or the type of access to health services) plays a crucial role in determining the specific health literacy-related challenges that migrants may encounter.

We will apply the integrated model of health literacy as an umbrella framework for assessing the effectiveness of health literacy interventions, focusing on the four steps of health information processing (access, understand, appraise and apply), and the involved cognitive, knowledge-based and motivational aspects that contribute to a person's health literacy.

Migration

We use the term migration as defined by the International Organization for Migration (IOM), which states that migration is "the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification" (IOM 2018a). Voluntary migration is often accompanied by the hope for improved living conditions for oneself or family members, better working opportunities, or study purposes. Forced migration can include coercion or obligation to flee from natural or human-made disasters, extreme poverty, religious, sexual or political persecution, generalised violence, or armed conflicts such as civil war (IOM 2018a; Moore 2004; Nuscheler 2013; Schouler-Ocak 2017). However, making a clear-cut distinction between forced and voluntary migration is not always feasible, since the complexity of individual experiences are often on a forced-voluntary continuum (Erdal 2018).

Independent from reasons for peoples' movement, migration is a life-changing experience that affects individual biographies, his or her family development, and shapes several following generations.

Migration includes risks and opportunities in social and economic conditions, as well as health (Razum 2008). Poor socio-economic environments and living conditions, limited access to educational opportunities, and psychological stresses such as chronic work hazards are well examined causal factors leading to health inequalities (Marmot 2005). These factors can have a particularly strong impact on migrants' health because language barriers, racial discrimination or limited health systems knowledge are significant challenges to health improvement and preservation, and recovery from illness (Derose 2007; Harris 2006; Masseria 2010; Timmins 2002). Although migrants are often, at least initially, relatively healthy compared to most people in the host country, international studies indicate that immigrants and refugees tend to be vulnerable to poor mental health, certain communicable diseases such as tuberculosis and HIV/AIDS, and non-communicable diseases such as diabetes, injuries and maternal and child health problems (Goosen 2014; Kirmayer 2011; Lindert 2009; Rechel 2013; Yun 2012). Certain migration trajectories are linked to specific health adversities and rates of health care experienced before, during, and after migration. For example, among refugees escaping from civil war the migration process can be accompanied by violence, exploitation by human traffickers, hunger, and infectious diseases (IOM 2013; United Nations 2017). Furthermore, accessing affordable high-quality healthcare in the host country can vary among health care systems and may depend on the legal status of the migrant (Bozorgmehr 2016; Rechel 2013; WHO 2010).

Although differing in intensity, gender differences occur in all cultures and can be of critical importance at all stages of the migratory process. However, certain health risks are more common among women (e.g. sexual violence and abuse, human trafficking, or risks around childbirth and pregnancy), whereas accidents, physical stress or work hazards affect men more commonly (Douki 2007; Llácer 2007; Malmusi 2010; Schouler-Ocak 2017). These circumstances can influence why people need health information, and affect how health information is accessed, processed and translated into health-related action.

Research on health literacy indicates that having a migrant background might not be the sole issue (Ganahl 2016), but seems likely to function as a multiplier in creating health inequalities. Health literacy has a social gradient, including social status, education, income, and age (Berkman 2011; HLS-EU Consortium 2012; Schaeffer 2017; Quenzel 2016). Some of these factors can be even more pronounced in the context of migration. However, generalising assumptions on migrants' health literacy should be avoided, as people differ in their experiences, educational background, socio-economic resources, and in their health status.

Considering equity in health literacy

A lack of evidence on equity has been described as a barrier to use of systematic reviews by health-decision makers (Welch 2015). Considering equity in systematic reviews on health literacy is therefore of high importance for the effective implementation of health literacy interventions. Equity is defined as "the absence of avoidable and unfair inequalities in health" (Welch 2012; Whitehead 1992). The emphasis of this concept is on the avoidance of unfair differences in health and related outcomes among individuals in a population and among different population groups. Differences in health across certain socio-demographic characteristics, including age, sex and gender, or ethnicity, can be caused by discrimination or inadequate access to health care services, which hinders people from preserving and regaining health (Welch 2015).

The integrated model of health literacy developed by Sørensen 2012 (see Description of the condition) draws attention to the importance of equity in health literacy research across individuals and populations. The integrated model will serve as an equity model for this review because it includes relevant personal determinants such as gender and race, socio-economic status and education, situational variables (e.g. the current physical environment), and culture as societal and environmental determinants of health literacy. The term *race*, albeit a scientifically unjustifiable concept (Williams 1997), that is used inconsistently throughout the literature (Williams 1994; Kaplan 2003), is often applied to denote immigrant groups such as so-called Hispanics/Latinos/Latinas (López 2010). If this term is accompanied by information that the person who was categorised by race is a migrant, we will use the term race (or the synonymous term 'ethnicity') as a personal determinant of health literacy. Thus, migration can be integrated in the model as a personal (i.e. race or ethnicity), situational (i.e. pre-, peri-, and post-migration status), or societal and environmental factor (i.e. culture) to determine health literacy.

We will follow the PRISMA-Equity (PRISMA-E) reporting guidelines for systematic reviews to acknowledge equity as an important determinant of health (Welch 2012; Welch 2015).

Description of the intervention

This review will assess different interventions with the purpose of improving individual health literacy in migrants or outcomes associated with at least one of the four health information processing steps from the integrated health literacy model developed by Sørensen 2012. These may include community-based health-related interventions, such as community education or schooling programs, and individual-based health-related interventions such as online provision of information, personal (face-to-face) provision of information, or others. Interventions can be delivered by any person involved in the health care or social work field and working closely with migrants and their descendents. Furthermore, the outcomes of these interventions should be measured using either an established assessment tool for health literacy as a construct, or an assessment tool that is capable of measuring the outcomes of the respective processing step that are targeted in the intervention. Health literacy could be assessed using remote (e.g. online, telephone) or face-to-face questionnaires or surveys. Interventions for improving health literacy that target health

care providers, services or information materials rather than the consumer, will be included only if the effects of such interventions are directly measured in female and male migrants (How the intervention might work). We will focus on interventions targeting individual health literacy. Broader interventions that address the health literacy environment solely, such as health literacy toolkits for health systems (Dodson 2015), or approaches to create health literate health care organisations exist (Brach 2012), but are beyond the scope of this review.

How the intervention might work

Specific design features of interventions targeted for low-health-literacy populations (e.g. presenting essential information first, presenting information in simple language or formats, or substantiated by video or illustrated narratives) have been shown to be effective in terms of improving comprehension of information. Furthermore, multiple interventions such as intensive self- and disease-management or adherence interventions, have shown promise to mitigate the effects of limited health literacy with regard to reduced emergency department visits and hospitalisations, and reduced disease prevalence (Berkman 2011; Sheridan 2011). A recent meta-analysis indicated that on average health literacy interventions significantly improved participants' health literacy (22%) and treatment adherence (16%) among those who participated in a health literacy intervention compared to those who did not. However, particular methodological and measurement moderators greatly affected the effect sizes of health literacy interventions on participants' level of health literacy. For instance, subjective health literacy measures showed higher effect sizes over objective measures and health literacy improvements were higher when participants self-assessed their health literacy compared to assessment by a clinician or other members of the clinical team (Miller 2016). Therefore, conclusions have to be drawn carefully, since the effects may be highly variable within the included studies.

Apart from interventions that aim to improve health literacy in a general sense, we will also include interventions that target at least one of the four steps of health information processing. Pathways for these interventions may include empowering people by strengthening their skills in accessing, understanding, appraising or applying health information. For example, a web navigation training intervention (imparting knowledge) has been shown to improve health information search strategies of people living with HIV/AIDS, thereby focusing on the improved ability to search for and find online information (Kalichman 2006). Reproductive health knowledge was strengthened by a health education intervention that aimed to improve understanding of health information (Mbizvo 1997). The appraisal of such information was enhanced by matching content presentation to the control health locus for recipients (Williams-Piehota 2004). Individually tailored information on behavioural change increased cholesterol screening rates and physical activity (Kreuter 1996).

A successful interaction with health care providers is dependent on the communication skills of the patient on the one hand (e.g. language proficiency) and those of the health care professionals on the other hand (e.g. use of plain language and taking time for explanation). Therefore, another pathway for improving migrant's health literacy can include improving health care providers' communication skills, rather than educating the individual migrants themselves. Such interventions can indirectly improve health literacy skills and in turn health-related outcomes through a patient-provider communication that is respectful and tailored to the patient's health literacy needs. For instance, Tavakoly 2018 found that health provider communication skills training significantly improved patient communication skills, self-efficacy, adherence to medication, and hypertension outcomes.

Beauchamp 2017 developed a three-step approach that identified health literacy issues of health professionals or consumers; developed appropriate interventions; and implemented, evaluated and improved these interventions by using Plan-Do-Study-Act (PDSA) cycles. Successful interventions involved one of the following four pathways: improvement of clinician skills and resources for health literacy, the active engagement of community volunteers to disseminate health promotion messages, the direct impact on consumers' health literacy, and the redesign of existing health care services. Such studies indicate that an individual's health literacy can be improved through both direct and indirect means.

Why it is important to do this review

Research on migrants' health is highly relevant to gain a better understanding of migrants' specific health care needs, and how to respond best and most efficiently to these needs. Understanding the effectiveness of available interventions and pathways through which they have their effects is of great interest for decision-makers in health care systems, who face the challenge of rolling out interventions for improving health literacy across populations. Furthermore, it is important to identify effective approaches for improving access, understanding, appraisal and application of health information by migrants, since an appropriate response to health care needs entails the proper application of the health information found. However, people with limited health literacy skills face considerable barriers in accessing high quality health information, understanding, appraising, and applying the information for their own health care decisions and behaviours (Friis 2016; HLS-EU Consortium 2012; Schaeffer 2017). These and other challenges should be identified in the research on migrants' health literacy to ensure equitable and humane health care systems on the one hand, and empowered individuals on the other hand.

There is no prior Cochrane effectiveness review on migrants' health literacy. There is a published Cochrane effectiveness review on interventions for improving consumers' online health literacy (Car

2011), and a published Cochrane protocol on interventions improving health literacy in people with kidney disease (Campbell 2016). However, we do not expect overlap among the reviews because health literacy is defined differently in each, and the phenomena and populations under study differ greatly.

Research on health literacy has the overarching aim of establishing common understanding of health literacy, informing development of appropriate assessment tools, and effective interventions to improve health literacy. Health literacy measurement is evolving and most international research is targeted to assess individuals' ability to function in the health care environment, mostly measuring functional health literacy (i.e. reading and writing abilities in the medical context) and neglecting procedural characteristics of the four health information processing steps in other than clinical settings (Guzys 2015; Haun 2014). Particularly, the theory-driven approach of applying the integrated model of health literacy as an umbrella framework to assess the effectiveness of interventions that address the four health information processing steps, has not yet been determined. This review can therefore contribute to a more profound understanding of health literacy as a multidimensional construct by identifying effective pathways and design features of interventions targeted for migrants that address the relevant health information processing steps sufficiently. As a result, evidence found in this review can aid the development of new interventions, which enable the improvement of health literacy equally and effectively across populations. Thus, we expect these findings to have relevant implications for different states and their health care systems, particularly in western, industrialised countries, that have experienced great waves of migration in recent years.

OBJECTIVES

- To assess the effectiveness of interventions for improving health literacy in migrants.
- To assess whether female or male migrants may respond differently to the identified interventions.

Such interventions must address health literacy either as a comprehensive construct or at least one of its four health information processing steps (access, understand, appraise, apply). However, we do not aim to equate general health literacy interventions that include a range of activities targeted to all of the four health information processing steps with interventions that aim to improve only one step (e.g. understand). We aim instead to create a comprehensive picture of the effect of health literacy interventions by applying the integrated model as an umbrella framework for a deductive analysis of the four steps of health information processing.

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METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster RCTs (trials in which groups of participants are randomised) (see Data collection and analysis), and quasi-RCTs (trials in which randomisation is attempted but subject to potential manipulation, such as allocating participants by day of the week, date or birth, or sequence of entry into trial). We anticipate that few, if any, RCTs will have been conducted in the context of health literacy and migration (e.g. if study populations include both migrants and non-migrants but not separately identified).

Types of participants

We will include migrants, referring to these people as immigrants, refugees, asylum seekers, wandering people and other individuals who migrated (first generation migrants). This corresponds with the definition by the International Organization for Migration (IOM), which states that migration is the "the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification" (IOM 2018a). Thus, movement within a state will be considered as migration only if it is embedded within the movement of a population.

We will include adults aged 18 years or over. We will apply no gender or ethnicity restrictions. We will exclude trials if fewer than 80% of participants are adults, and if no subgroup data are available.

Studies that include only extractable data about individuals of established ethnic minority communities (e.g. Latino Americans in the USA), defined as descendants of migrants who have settled in the respective country at least one generation ago, will be excluded. If data for subgroups, who are explicitly designated as first generation migrants can be extracted, the study will be included.

We will include studies in which at least 80% of participants are migrants according to our definition. If no clear distinction between ethnic minority group and the migrant status according to our definition can be made (e.g. whether it is not stated which migrant generation is targeted), the study will be excluded.

Types of interventions

Eligible studies for inclusion can entail, for instance, interventions that aim to:

- improve health literacy in different settings (e.g. group-based education programs for pregnant women on post-partum care in an immigrant community);
- improve health literacy in hard-to-reach groups (e.g. telephone interventions to improve patients' engagement in disease management);
- improve health professionals' communication skills in consulting patients with low literacy skills (e.g. teach-back training, if the effect was measured in migrants);
- improve access to health information (e.g. access to telemedicine in rural areas);
- improve knowledge or understanding of information about health, disease or treatment (e.g. mitigate effects of limited language proficiency through the provision of information in different languages);
- affect the appraisal of health information (e.g. by individually tailoring the information provided); and
- improve the use of health information (e.g. providing information to support antibiotic treatment adherence).

For the main analysis, we will include health literacy interventions that are explicitly named as such. Such interventions can address health literacy either as a general concept, or at least one of its four health information processing steps (access, understand, appraise and apply).

For the secondary deductive analysis, we will include health literacy interventions that address at least one of the four health information processing steps, even if they are not explicitly named as such, so long as the addressed processing step can be assigned to health literacy as an umbrella concept. For example, if a study reports a 'health literacy intervention' as simply providing an information pamphlet on an available health service and reports a health literacy measure, we will include the study, but it will most likely not be suitable for the main analysis, since the effect cannot be assigned to health literacy as a general concept. This study will rather be included in the deductive analysis, as the intervention targets only the health information processing step 'access'. We will also include the study in the deductive analysis, if the pamphlet is targeted to individuals with limited language proficiency and the effect that is measured is the level of understanding that these individuals achieve regarding the information provided. In this case, the intervention will be assigned to the processing step of 'understand' in the deductive analysis.

We will exclude interventions that solely address the health literacy environment, i.e. interventions that focus on health care organisations or health systems without measuring the effect of these interventions on migrants' health literacy.

Types of comparisons

The types of comparisons will include the following:

- health literacy intervention versus no intervention (including usual care); and
- health literacy intervention versus another health literacy intervention.

Types of outcome measures

Outcome categories refer to empirically indicated associations of health literacy with the respective outcome category (Berkman 2011; HLS-EU Consortium 2012; Paasche-Orlow 2007; Paasche-Orlow 2005; Sheridan 2011). Applied health literacy assessment tools can be either performance-based or perception-based (self-assessment). We will prioritise validated (health literacy) assessment tools in preference to non-validated assessment tools. However, we will not exclude studies based on whether the assessment tool used has been validated or not.

If single trials report more than one outcome that maps to the same category we will list all reported outcomes. If an outcome is measured in more than one way in a single trial (e.g. pill count,

prescription refill, self-report), we will report these outcomes narratively for each included study, but we will prioritise objective outcome measures (e.g. blood glucose level, pill count) in preference to subjective outcome measures (e.g. self-reported medication taking). All outcomes reported in the included studies will be assigned independently to the review's outcome categories. Any differences in categorisation will be resolved by the involvement of a third review author. We will conduct a meta-analysis if at least two studies measure the same outcome in the same way (see Data synthesis). If more than one outcome per category per trial is eligible for meta-analysis, we will prioritise objective measures in preference to subjective measures so to not double-count data for the same outcome category for the same population in one analysis.

Primary outcomes

Primary outcomes include:

- Health literacy.
- Adverse events associated with the intervention (e.g. anxiety, stigmatisation).

Secondary outcomes

Secondary outcomes include:

- Quality of life.
- Health outcome (e.g. severity of disease, subjective health status, depression).
- Health behaviour (e.g. use of preventive measures, smoking rate, medication adherence).
- Health-related knowledge (e.g. disease-specific knowledge).
- Health service use (e.g. use of emergency room services, hospitalisation rate).
- Individual skills (e.g. self-efficacy, self-awareness).
- Health care costs.

Main outcomes for 'Summary of findings' table:

- Health literacy;
- Adverse events associated with the intervention (e.g. anxiety, stigmatisation);
- Quality of life;
- Health outcome (e.g. severity of disease, subjective health status, depression);
- Health behaviour (e.g. use of preventive measures, exercising rate, medication adherence);
- Health service use (e.g. use of emergency room services, hospitalisation rate);
- Health-related knowledge (e.g. disease-specific knowledge); and
- Individual skills (e.g. self-efficacy, self-awareness).

Timing of outcome assessment

We will include all time points of outcome assessment in this review and categorise them into short-, medium-, and long-term time points, if applicable.

Search methods for identification of studies

Electronic searches

We will adapt search strategies as suggested in Chapter Six of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011). The search strategy will be developed by an information specialist in consultation with the review authors. The concept of health literacy has evolved continuously since its first mention in 1974. Thus, we will search for studies that measure health literacy as a comprehensive concept, or one of its processing steps, even if these are not explicitly mentioned as such in the respective study. We will include full-text articles and publications available as abstracts only if sufficient information is available on study design, characteristics of participants, and interventions provided.

We will search the following electronic databases:

- The Cochrane Central Register of Controlled Trials (CENTRAL, the*Cochrane Library*) (Appendix 1);
- MEDLINE (OvidSP) (Appendix 2);
- PsycINFO (OvidSP) (Appendix 3) and
- CINAHL (EBSCO) (Appendix 4).

The search strategy contains a study filter for RCTs and will be adapted to each database. No date, language or geographic restrictions will be applied for the search.

Searching other resources

We will search reference lists of included studies and relevant systematic reviews.

We will also search online trials registers for ongoing and recently completed studies:

- ClinicalTrials.gov;
- WHO International Clinical Trials Registry Platform (ICTRP); and
- EU Clinical Trials Register.

We will also search conference proceedings of the following conferences:

- International Conference for Migration and Development;
- First World Congress on Migration, Ethnicity, Race And Health (MERH);
- European Public Health Conference (EUPH); and
- The Migration Conference.

Data collection and analysis

Selection of studies

Two review authors will independently screen all titles and abstracts identified from searches to determine which meet the inclusion criteria. We will retrieve the full text of any papers identified as potentially relevant by at least one review author. Two review authors will independently screen full text articles for inclusion or exclusion, with discrepancies resolved by discussion, and if necessary, by consultation with a third review author to reach consensus (Higgins 2011). All potentially-relevant papers excluded from the review at this stage will be listed as excluded studies, with reasons provided in the 'Characteristics of excluded studies' table. We will document the process of study selection in a flow chart, as recommended by the PRISMA statement (Liberati 2009), showing total numbers of retrieved references and numbers of included and excluded studies. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in this review.

Data extraction and management

Two review authors will extract data independently from included studies. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third review author where necessary. We will develop and pilot a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at: http://cccrg.cochrane.org/author-resources). The data extraction form will be pilot tested with the first five included studies, and refined as necessary.

Data to be extracted will include:

- General information: author, title, source, publication date, country, language, duplicate publications
- Quality assessment (risk of bias): allocation concealment, blinding (participants, personnel, outcome assessors), incomplete outcome data, selective
- outcome reporting, other sources of bias (e.g. methods of measurements)
- Study characteristics: trial design, aim of the intervention, setting and dates, source of participants, inclusion/exclusion criteria, random sequence generation, selective recruitment of cluster participants, subgroup analysis, treatment
- cross-overs, compliance with assigned intervention, length of follow-up, details of control group characteristics e.g. recruitment and selection strategy, types of comparisons (e.g. waiting list control).
- Participant characteristics: age, gender, ethnicity, number of participants recruited/allocated/evaluated, participants lost to follow-up, type of intervention
- Outcomes: primary outcomes: health literacy and adverse events; secondary outcome categories: quality of life, health outcome, health behaviour, health-related knowledge, health service use, individual skills, health care costs
- Data extraction by outcome: use of validated assessment tool, timing of outcome assessment
- Funding: details of the funding source, declaration of interests for the primary investigators

All extracted data will be entered into RevMan 5 (Review Manager 2014) by one review author, and will be checked for accuracy against the data extraction sheets by a second review author working independently. We will contact authors of individual studies to ask for additional information if required.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane *Handbook* (Higgins 2011), and Cochrane Consumers and Communication guidelines (Ryan 2013), which recommend the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias such as health literacy measurement (e.g. social desirability in self-assessment tools). We will consider blinding separately for different outcomes where appropriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures). We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the risk of bias table.

Studies will be deemed to be at the highest risk of bias if they are scored as at high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011). We will assess and report quasi-RCTs as being at a high risk of bias on the random sequence generation item of the risk of bias tool. For cluster-RCTs we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants.

In all cases, two review authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgment about the internal validity of the review's results.

Measures of treatment effect

For dichotomous outcomes, we will analyse data based on the number of events (e.g. mortality, hospitalisation rates) and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). Where continuous scales of measurement are used (e.g. health literacy measurement, length of hospital stay) we will analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the inverse variance method in RevMan 5.

Unit of analysis issues

We will check for unit-of-analysis errors if cluster-RCTs are included. If errors are found, and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis, by taking account of the intra-cluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it not possible to obtain sufficient information to re-analyse the data, we will report effect estimates and annotate as unit-of-analysis error.

Dealing with missing data

We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, where possible we will conduct analysis on an intention-to-treat basis, otherwise data will be analysed as reported. We will report on losses to follow-up and assess this as a source of potential bias. For missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

Assessment of heterogeneity

Where studies are considered to be similar enough to allow pooling of data using meta-analysis (based on consideration of migration status, health literacy interventions or gender), we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. We will report our reasons for deciding that studies were similar enough to pool statistically. Heterogeneity will be quantified using the I^2 statistic. An I^2 value of 50% or more will be considered to represent substantial heterogeneity, but this value will be interpreted in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi^2 test (Higgins 2011). Where heterogeneity is present in pooled effect estimates we will explore possible reasons for variability by conducting subgroup analysis.

Where we detect substantial clinical, methodological or statistical heterogeneity across included studies we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event, we will clearly report our reasons for deciding that studies were too dissimilar to meta-analyse. We will also attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of migrant populations, host countries, intervention features, methodological features, or other factors to explore differences in intervention effects.

Assessment of reporting biases

We will assess reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information obtained from contacting experts and authors of studies suggests there are relevant unpublished studies.

If we identify sufficient studies (at least 10) for inclusion in the review, we will construct a funnel plot to investigate small study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice from the Cochrane *Handbook* (Higgins 2011), and bearing in mind there may be several reasons for funnel plot asymmetry when interpreting the results.

Data synthesis

We will decide to meta-analyse data based on whether the interventions in the included trials are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in different migrant populations, health literacy and outcome measurements, and health literacy interventions of included studies, we will use a random-effects model for meta-analysis.

If we are unable to pool data statistically using meta-analysis, we will provide clear reasons for this decision, and will group data based on the category that best explores the heterogeneity of studies and makes most sense to the reader (i.e. by interventions, migrant populations or outcomes). We will present data in tables and narratively summarise the results for each category.

Subgroup analysis and investigation of heterogeneity

If possible, we will conduct subgroup analyses for gender, ethnicity, and health literacy assessment (if named as such) (Objectives). Since health literacy can be defined and measured in different ways we will conduct a subgroup analysis for the different measurement

tools applied in the included studies. Health literacy assessment tools may include performance-based assessment tools such as the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis 1991), that measure reading and writing abilities in the medical context. Perception-based assessment tools such as the Health Literacy Questionnaire (HLQ) (Osborne 2013), or the European Health Literacy Questionnaire (HLS-EU-Q) (Sørensen 2013), measure self-reported health literacy, including, for instance, the assessment of self-perceived difficulties in processing health information with regard to health promotion, disease prevention, and disease management (Sørensen 2013).

Sensitivity analysis

If meta-analysis is possible, we will conduct a sensitivity analysis for high risk and low risk of bias studies (see Assessment of risk of bias in included studies).

'Summary of findings' table

We will prepare a 'Summary of findings' table to present the results of meta-analysis and/or narrative synthesis for the major comparisons of the review, for each key outcome including potential harms, as (see Types of outcome measures). We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE criteria to rank the quality of the evidence based on the methods described in chapter 11 of the Cochrane *Handbook* (Schünemann 2011), using GRADEpro GDT software. If meta-analysis is not possible, we will present results as a narrative in a 'Summary of findings' table.

Involvement of consumers

This review is part of an overarching project which aims to examine gender-specific health literacy in migrants by applying a mixed methods approach. The project is funded by the Federal Ministry of Education and Research in Germany.

The involvement of consumers is important to get a deeper understanding of the performance and effectiveness of the interventions in this review, particularly how they reach consumers. We will involve consumers by conducting additional qualitative research to support our review, and particularly the interpretation of our findings. We will conduct gender-separate focus group discussions with female and male migrants, in which we will present and discuss our findings in order to reflect on our analysis. The protocol and review will receive feedback from at least one consumer referee in addition to a health professional as part of Cochrane Consumers and Communication's standard editorial process.

In a final symposium of this project, we want to present our primary and secondary research findings to experts in the political and health care context, and discuss the impact and implications of our primary and secondary findings for health care decision-making at the political level particularly in Germany. We expect our findings to contribute to relevant political decisions for the health care of migrants in Germany, and also provide implications for other health care systems as well.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MESH DESCRIPTOR TRANSIENTS AND MIGRANTS EXPLODE ALL TREES
#2 migrant*
#3 migration* NEAR3 (background* or human*)
#4 MESH DESCRIPTOR EMIGRANTS AND IMMIGRANTS EXPLODE ALL TREES
#5 MESH DESCRIPTOR UNDOCUMENTED IMMIGRANTS EXPLODE ALL TREES
#6 MESH DESCRIPTOR EMIGRATION AND IMMIGRATION EXPLODE ALL TREES
#7 (immigrant* or immgrat*)
#8 (emigrant* or emigrat*)
#9 (minorit* NEAR3 (population* or group*))
#10 ethnic* NEAR3 (population* or group* or patient* or background* or specific* or minorit* or identit*)
#11 ethnic* NEAR3 (population* or group* or patient* or background* or specific* or minorit* or identit*)
#11 displaced and (people or person*)
#12 MESH DESCRIPTOR VULNERABLE POPULATIONS EXPLODE ALL TREES
#13 MESH DESCRIPTOR REFUGEES EXPLODE ALL TREES
#14 foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn
#15 cultur* NEAR5 (differences* or cross* or background*)
#16 cultur* NEAR5 (differences* or cross* or background*)
#16 (border* and crossing)
#17 (culturall* NEAR3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*))
#18 linguisticall* NEAR3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)
#19 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18
#20 MESH DESCRIPTOR ACCESS TO INFORMATION EXPLODE ALL TREES
#21 (access or gain access or obtain or seek out or find or indentify) NEAR5 (information* or health*)
#22 MESH DESCRIPTOR COMPREHENSION EXPLODE ALL TREES
#23 understand or comprehend or comprehension
#24 appraise or evaluate or process or interpret or assess
#25 assessment of information
#26 apply or decide
#27 use* NEAR3 (information* or health)
#28 MESH DESCRIPTOR DECISION MAKING EXPLODE ALL TREES
#29 (make or making or made or take) NEAR4 decision*
#30 acting or act or action
#31 judge*
#32 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31
#33 MESH DESCRIPTOR CONSUMER HEALTH INFORMATION EXPLODE ALL TREES
#34 MESH DESCRIPTOR INFORMATION LITERACY EXPLODE ALL TREES
#35 MESH DESCRIPTOR HEALTH LITERACY EXPLODE ALL TREES
#36 information* NEAR3 health*
#37 health* NEAR3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)
#38 #33 OR #34 OR #35 OR #36 OR #37
#39 MESH DESCRIPTOR HEALTH EDUCATION EXPLODE ALL TREES
#40 MESH DESCRIPTOR EDUCATIONAL STATUS EXPLODE ALL TREES
#41 health* NEAR3 education*
#42 MESH DESCRIPTOR HEALTH SERVICES ACCESSIBILITY EXPLODE ALL TREES
#43 #39 OR #40 OR #41 OR #42
#44 #32 and #38 or #43

#45 health litera*
#46 medical literacy
#47 ((health and literacy)):TI
#48 ((functional and health and literacy)):TI,AB,KY
#49 low-litera*
#50 litera*
#51 illitera*
#52 MESH DESCRIPTOR READING EXPLODE ALL TREES
#53 MESH DESCRIPTOR COMPREHENSION EXPLODE ALL TREES
#54 MESH DESCRIPTOR HEALTH PROMOTION EXPLODE ALL TREES
#55 MESH DESCRIPTOR HEALTH EDUCATION EXPLODE ALL TREES
#56 MESH DESCRIPTOR PATIENT EDUCATION AS TOPIC EXPLODE ALL TREES
#57 MESH DESCRIPTOR COMMUNICATION BARRIERS EXPLODE ALL TREES
#58 MESH DESCRIPTOR COMMUNICATION EXPLODE ALL TREES
#59 MESH DESCRIPTOR ATTITUDE TO HEALTH EXPLODE ALL TREES
#60 MESH DESCRIPTOR COMPREHENSION EXPLODE ALL TREES
#61 MESH DESCRIPTOR EDUCATIONAL STATUS EXPLODE ALL TREES
#62 #60 AND #61
#63 family and literacy
#64 drug labeling
#65 MESH DESCRIPTOR DRUG PRESCRIPTIONS EXPLODE ALL TREES
#66 comprehension
#67 (cancer or diabetes or genetics) and (literacy or comprehension)
#68 adult and (educational status or (educational and status) or literacy)
#69 (limited and (educational status or (educational and status) or literacy))
#70 (patient* and (educational status or (educational and status) or literacy))
#71 (patient* and (comprehension or understanding))
#72 #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53
#73 #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71
#74 #72 AND #73
#75 #19 and #44
#76 #19 and #74
#77 #19 and #44 or #74
#77 #75 or #76

Appendix 2. MEDLINE search strategy

searches
1 “TRANSIENTS AND MIGRANTS”/
2 migrant*.tw,kf,ot.
3 (migration* adj3 (background* or human*)).tw,kf,ot.
4 exp “EMIGRANTS AND IMMIGRANTS”/
5 UNDOCUMENTED IMMIGRANTS/
6 “EMIGRATION AND IMMIGRATION”/
7 (immigrant* or immgrat*).tw,kf,ot.
8 (emigrant* or emigrat*).tw,kf,ot.
9 (minorit* adj3 (population* or group*)).tw,kf,ot.
10 (ethnic* adj3 (population* or group* or patient* or background* or specific* or minorit* or identit*)).tw,kf,ot.
11 (displaced and (people or person$1)).tw.
12 VULNERABLE POPULATIONS/
13 REFUGEES/

14 (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn).tw,kf,ot.
15 (cultur* adj5 (differences* or cross* or background*)).tw,kf,ot.
16 (border* and crossing).tw.
17 ((culturall* or linguisticall*) adj3 (diverse* or patient* or parent* or communit* or background* or student* or wom?n or famil*)).tw,kf,ot.
18 or/1-17
19 ACCESS TO INFORMATION/
20 ((access or gain access or obtain or seek out or find or identify) adj5 (information* or health*)).tw.
21 COMPREHENSION/
22 (understand or comprehend or comprehension).tw.
23 (appraise or evaluate or process or interpret or assess).tw.
24 assessment of information.tw.
25 (apply or decide).tw.
26 (use* adj3 (information* or health)).tw.
27 (capacit* adj4 health).tw.
28 accept*.tw,kf,ot.
29 DECISION MAKING/
30 ((make or making or made or take) adj4 decision*).tw.
31 ("behavior change" or "behaviour change").tw,kf,ot.
32 (acting or act or action).tw.
33 judge*.tw.
34 or/19-33
35 exp CONSUMER HEALTH INFORMATION/ or INFORMATION LITERACY/
36 HEALTH LITERACY/
37 (information* adj3 health*).tw.
38 (health* adj3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)).tw.
39 or/35-38
40 HEALTH EDUCATION/ or EDUCATIONAL STATUS/
41 (health* adj3 education*).tw.
42 HEALTH SERVICES ACCESSIBILITY/sn [Statistics & Numerical Data]
43 or/40-42
44 34 and (39 or 43)
45 health litera$2.af.
46 medical literacy.af.
47 (health and literacy).ti.
48 (functional and health and literacy).tw.
49 low-litera$2.ti.
50 litera$2.ti.
51 illitera$2.ti.
52 READING/
53 COMPREHENSION/
54 *HEALTH PROMOTION/
55 *HEALTH EDUCATION/
56 *PATIENT EDUCATION/
57 *COMMUNICATION BARRIERS/
58 *COMMUNICATION/
59 *HEALTH KNOWLEDGE,ATTITUDES,PRACTICE/
60 *ATTITUDE TO HEALTH/
61 *COMPREHENSION/ and *EDUCATIONAL STATUS/
62 (family and literacy).ti.
63 (drug labeling.af. or DRUG PRESCRIPTIONS/) and comprehension.af.
64 ((cancer or diabetes or genetics) and (literacy or comprehension)).ti.

65 (adult and (educational status or (educational and status) or literacy)).af.
66 (limited and (educational status or (educational and status) or literacy)).af.
67 (patient$1 and (educational status or (educational and status) or literacy)).af.
68 (patient$1 and (comprehension or understanding)).ti.
69 or/45-53
70 or/54-68
71 69 and 70
72 18 and 44
73 18 and 71
74 18 and (44 or 71)
75 randomized controlled trial.pt.
76 controlled clinical trial.pt.
77 randomi?ed.ab.
78 placebo.ab.
79 drug therapy.fs.
80 randomly.ab.
81 trial.ab.
82 groups.ab.
83 or/75-82
84 exp ANIMALS/ not HUMANS/
85 83 not 84
86 74 and 85
87 from 86 keep 1-136
Key: tw: text word, kf: keyword heading word, ot: original title, ti: title, pt: publication type, ab: abstract, fs: floating subheading, hw: subject heading word, nm: name of substance word, sh: MeSH subject heading

Appendix 3. PSYCHINFO search strategy

Query
S74 S72 AND S73
S73 TX control OR TX random OR TX double-blind
S72 S18 and (S44 or S71)
S71 S69 and S70
S70 S54 or S55 or S56 or S57 or S58 or S59 or S60 or S61 or S62 or S63 or S64 or S65 or S66 or S67 or S68
S69 S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53
S68 TI (patient* and (comprehension or understanding))
S67 SU (patient* and (educational status or (educational and status) or literacy))
S66 SU (limited and (educational status or (educational and status) or literacy))
S65 SU (adult and (educational status or (educational and status) or literacy))
S64 TI (cancer or diabetes or genetics) and (literacy or comprehension)
S63 SU (drug labeling or prescriptions, drugs) and comprehension
S62 TX family and literacy
S61 MA COMPREHENSION AND MA EDUCATIONAL STATUS
S60 MA "HEALTH PERSONNEL ATTITUDES"
S59 DE "HEALTH ATTITUDES"
S58 DE "HEALTH KNOWLEDGE" OR DE "HEALTH BEHAVIOR"
S57 DE COMMUNICATION
S56 DE COMMUNICATION BARRIERS
S55 DE HEALTH EDUCATION
S54 DE HEALTH PROMOTION
S53 DE COMPREHENSION
S52 DE READING

S51 TX illitera*
S50 TX literac*
S49 TX low-litera*
S48 TX functional and health and literacy
S47 TX health and literacy
S46 TX medical literacy
S45 TX health litera*
S44 S34 and (S39 or S43)
S43 S40 or S41 or S42
S42 MA HEALTH SERVICES ACCESSIBILITY
S41 TX health* N3 education*
S40 DE HEALTH EDUCATION OR (DE EDUCATION AND DE STATUS)
S39 S35 or S36 or S37 or S38
S38 TX health* N3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)
S37 TX information* N3 health*
S36 DE HEALTH LITERACY
S35 MA CONSUMER HEALTH INFORMATION OR DE INFORMATION LITERACY
S34 S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33
S33 TX judge*
S32 TX acting or act or action
S31 TX "behavior change" or "behaviour change"
S30 TX ((make or making or made or take) N4 decision*)
S29 DE DECISION MAKING
S28 TX accept*
S27 TX capacit* N4 health
S26 TX use* N3 (information* or health)
S25 TX apply or decide
S24 TX assessment of information
S23 TX appraise or evaluate or process or interpret or assess
S22 TX (understand or comprehend or comprehension)
S21 DE COMPREHENSION
S20 TX (access or gain access or obtain or seek out or find or indentify) N5 (information* or health*)
S19 MA "ACCESS TO INFORMATION"
S18 S1 or S2 or S3 Or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
S17 TX (culturall* or linguisticall*) N3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)
S16 TX border* and crossing
S15 TX cultur* N3 (differences* or cross* or background*)
S14 TX (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn)
S13 DE REFUGEES
S12 MA VULNERABLE POPULATIONS
S11 TX (displaced and (people or person*))
S10 TX ethnic* N2 (population* or group* or patient* or background* or specific* or minorit* or identit*)
S9 TX minorit* N2 (population* or group*)
S8 TX emigrant* OR TX emigrat*
S7 TX immigrant* OR TX immgrat*
S6 DE IMMIGRATION
S5 DE HUMAN MIGRATION
S4 MA "EMIGRANTS AND IMMIGRANTS"
S3 TX migration* N3 (background* or human*)
S2 TX migrant*
S1 MA "TRANSIENTS AND MIGRANTS"

Key: TX: all text, TI: title, DE: subject (exact), SU: subjects, MA: MeSH subject heading

Appendix 4. CINAHL search strategy

Query
S83 S80 AND S81
S82 S81
S81 S18 and (S44 or S70)
S80 S71 OR S72 OR S73 OR S74 OR S75 OR S76 OR S77 OR S78 OR S79
S79 TX ((singl* n1 blind*) or (singl* n1 mask*)) o(doubl* n1 blind*) or (doubl* n1 mask*) or (tripl* n1 blind*) or (tripl* n1 mask*) or (trebl* n1 blind*) or (trebl* n1 mask*)
S78 TX randomi?ed
S77 (MH "Random Assignment")
S76 TX random* allocat*
S75 (MH "Randomized Controlled Trials")
S74 TX placebo*
S73 (MH "Placebos")
S72 (MH "Quantitative Studies")
S71 TX allocat* random*
S70 S68 AND S69
S69 S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67
S68 S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53
S67 TI (patient* and (educational status or (educational and status) or literacy))
S66 MW (patient* and (educational status or (educational and status) or literacy))
S65 TI (limited and (educational status or (educational and status) or literacy))
S64 MJ (adult and (educational status or (educational and status) or literacy))
S63 TI (cancer or diabetes or genetics) and (literacy or comprehension)
S62 TX ((drug labeling or prescriptions, drug) and comprehension)
S61 TI family and literacy
S60 (MM "Educational Status") AND TX comprehension
S59 (MM "Attitude to Health")
S58 (MM "Health Knowledge")
S57 (MM "Communication")
S56 (MM "Communication Barriers")
S55 (MM "Health Education")
S54 (MM "Health Promotion")
S53 TX comprehension
S52 MH READING
S51 TI illitera*
S50 TI litera*
S49 TI low-litera*
S48 TX functional and health and literacy
S47 TI health and literacy
S46 TX medical literacy
S45 TX health litera*
S44 S34 and (S39 or S43)
S43 S40 or S41 or S42
S42 (MH "Health Services Accessibility")
S41 TX health* N3 education*
S40 (MH "Health Education") OR (MH "Educational Status")
S39 S35 or S36 or S37 or S38

S38 TX health* N3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)
S37 TX information* N3 health*
S36 (MH "Health Literacy")
S35 (MH "Consumer Health Information") OR (MH "Information Literacy")
S34 S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33
S33 TX judge*
S32 TX acting or act or action
S31 TX "behavior change" or "behaviour change"
S30 TX ((make or making or made or take) N4 decision*)
S29 (MH "Decision Making, Family") OR (MH "Decision Making, Patient")
S28 TX accept*
S27 TX capacit* N4 health
S26 TX use* N3 (information* or health)
S25 TX apply or decide
S24 TX assessment of information
S23 TX appraise or evaluate or process or interpret or assess
S22 TX understand or comprehend
S21 TX comprehension
S20 TX (access or gain access or obtain or seek out or find or identify) N5 (information* or health*)
S19 (MH "Access to Information")
S18 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
S17 TX (culturall* or linguisticall*) N3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)
S16 TX border* and crossing
S15 TX cultur* N5 (differences* or cross* or background*)
S14 TX (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn)
S13 (MH "Refugees")
S12 (MH "Population") AND (MH "Vulnerability")
S11 TX (displaced and (people or person*))
S10 TX ethnic* N3 (population* or group* or patient* or background* or specific* or minorit* or identit*)
S9 TX minorit* N3 (population* or group*)
S8 TX emigrant* OR TX emigrat*
S7 TX immigrant* OR TX immgrat*
S6 (MH "Emigration and Immigration")
S5 MH "Immigrants, Illegal"
S4 MH "EMIGRANTS AND IMMIGRANTS"
S3 TX migration* N3 (background* or human*)
S2 TX migrant*
S1 MH "TRANSIENTS AND MIGRANTS"
key: TX: all text, TI: title, MH: CINAHL exact subject heading, MM: CINAHL exact major subject headings, MJ: CINAHL word in major subject heading, MW: CINAHL heading word

CONTRIBUTIONS OF AUTHORS

Annika Baumeister developed and wrote the protocol.

Angela Aldin assisted in developing the protocol, proofread and commented on the draft.

Digo Chakraverty proofread and commented on the draft.

Ina Monsef developed the search strategies.

Tina Jakob proofread and commented on the draft.

Ümran Sema Seven provided expertise on migration research.

Görkem Anapa provided expertise on migration research.

Elke Kalbe proofread and commented on the draft.

Nicole Skoetz proofread and commented on the draft.

Christiane Woopen proofread and commented on the draft.

DECLARATIONS OF INTEREST

Annika Baumeister: Award of the grant by Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Angela Aldin: Award of the grant by Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Digo Chakraverty: Award of the grant by Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Ina Monsef: none known.

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